IAP 3737

ATTN: Mr. Brian Casler

Dear Sir,

I am writing to you this letter due to my concern regarding quality of expertise and qualification of your examiner(s) who reviewed my patent "Apparatus and method for spectroscopic analysis of human and animal tissue or body fluids."

Serial No.: 09/817,361.
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I got rejection of my claims in the patent during several years due to completely incompetent analysis of my patent by of examiner(s). Examiner sent me a lot of patents of other authors thinking that these patents are coincided with my idea and method.

It was, for example, the patent of Kittrell et al (US 5,304,173) who disclosed fluorescence spectral system and laser catheter which has no any close relation to my patent. Other patents were also quite different from my idea and results. I can send you all my detailed evaluations of these patents of other authors and difference from my patent. For example, a lot of endoscopes and catheters can be around. But I suggested infrared (IR) endoscope with silver halide fibers (enough thick fibers) inside in the combination with Fourier Transform Infrared (FTIR) spectrometer, and showed my results a new way in molecular diagnostics. .

Last years the examiner of my patent is Ms (or Mrs.) Ruth Smith. I deeply appreciated to her revision of my patent. Specifically she is "brilliant" in her bureaucratic analysis from point of vie words in my patent and a lot of so-called "parallel" patents of other authors which she sent me a lot. Now R. Smith sent me rejection due to Rava et al patent (6,690,966) where she was an examiner. This patent is about Raman method but not infrared (IR) spectroscopy method what about is my patent. Rava's claims are only cover Raman method, specifically near-IR (NIR) FT-Raman with optical fibers for Raman technique that are much easy for manufacturing from other materials than IR fibers. . The group of Prof Michel S. Feld is very well known in laser method(s) for treatment of atherosclerosis problems, and Raman detection of the tissue. **Therefore all claims in Rava patent are regarding Raman method, not about IR.**

But Rava et al understood during last years that it is not enough only Raman method for their studies. Infrared is very informative for bio-analysis due to specificity of vibrations Modes, bands) which we can see in the IR range. IR method is much more informative than Raman in many cases (bio-samples, polymers, and so on). Therefore Rava included IR method in his description of his analysis with words how infrared method could be useful. This group used only a standard commercial horizontal ATR accessory with FTIR spectrometer for their analysis. It is impossible to do in vivo measurements with this standard ATR accessory as R. Smith wrote me with the reference on column12, lines

61-63 of Rava et al patent. She wrote me that again and again. Does R. Smith know this ATR accessory? In ATR accessory you can put only a small part of your finger (with nail) for in vivo analysis. How it is possible to do the measurements of moles, spots, and other areas of malignant or normal tissues directly from surface of the body? But I showed that in my patent. Could somebody put their neck or a part of the face, or arm in ATR accessory??? What signal do you get, what do you think about it??? It is completely incompetent remark of R. Smith. As for the figures 16a-b, column 13, lines 14-43, of Rava et al patent, they have ATR element in the end of their fiber, ZnSe-element, which could be toxic. I have in my patent only flexible loop of the same nontoxic silver halide fiber. This is much more simple and productive way.

I apply (attach) all my remarks separately regarding Rava et al patent for your information.

Formally it is obviously that Rava et al patent (6,690,966 B1) is from Feb 10, 2004 but my patent is from 2001. Please take that into your account.

My patent from 2001 is the second version of my patent. The first one was from 1997/98 (pending), passed examination from your Main Patent Office without any rejection, and has to be issued in the fall 2000 or in the beginning 2001. But I withdraw my first version due to a lot of claims (55) and conflict of interests with Dr. R. Bruch who did not contribute anything to these results. He is not s specialist in this field. He invited me in 1996 to work with him for the University of Nevada/Reno (Physics Dept). Bruch knew that I have several new directions in physics and wanted to use them. Sierra Patent Office (Dr. Kenneth D'Alessandro) and Dept of Physics know about it very well. Sierra Patent Office helped me to file again my patent in 2001 to decrease the number of claims and be free from the name of Bruch. My results are from 1993-96 from Russia. I worked in hospital for oncology and histopathology with the medical doctors. Other my results in my current version of the patent are from the US (University of Nevada/Reno and SpectroOptical Sensing Inc. (Portland, OR)

Now I have from R. Smith the patent of S.G. Krivoshlykov (6,016,197 from Jan.18, 2000) about an analyzer where is the examiner found silver halide optical fibers which I used early than this author. Again, I did not invent any analyzer in my patent. I used commercially available silver halide fibers but under my spectral control of their quality. Silver halide fiber is intricate due to polycrystalline material for fibers and specific procedure of their manufacturing. Dr. S. Artjushenko worked for CeramOptec Inc. He brought these fibers to them. I have the reference to his patent in my patent.

Patents of Krivoshlykov and/or Rava /and/or somebody else which I got from your Office are not crossing way of my patent and my patent is not crossing their patents. They are very good also **but completely different from mine.**

Unfortunately we have no "golden" (or "gold") analytical methods specifically for analysis of living tissues non-invasively and in vivo (that is about my patent). It is much more easily to do combination of commercially available optical fibers to Raman

spectrometer than to do similar combination for mid-IR spectral range due to limitation of IR materials for such fibers. We have also the limitation regarding the detection of weak signals in the mid-IR region specifically for biological tissue. Briefly about my invention: this invention is about non-invasive and in vivo detection of any size of living tissue directly from the surface via combination of soft, flexible, non-toxic infrared fibers and FTIR spectrometer in a distance (remote) in the regime of internal (attenuated) total reflection (ATR-regime), also called evanescent wave regime. Many years ago in 1960s the American Classic and Father of the method of internal reflection spectroscopy Prof N.J. Harrick wrote in his book (Harrick, N.J.1967, Internal reflection Spectroscopy: John Wiley and Sons, Inc. New York) how difficult to realize internal reflection regime in rod or optical fiber. I did it in 1990s for living tissue (not for samples which are possible to analyze only in vitro as it can be done with traditional ATR accessory with a long procedures of "sample preparation"). But in my method I can only touch by soft, flexible loop of optical fiber (of different configurations) any place of human body and during 15 sec do the definition of normal and/or abnormal living tissue via IR spectra in the entire mid-IR range. I also showed in my patent which specific vibrations (bands) and their intensities of the bands are more suitable for early diagnostics of malignancy for living tissue in vivo and non-invasively with these optical fibers. **We have no differences in IR spectra working with good quality silver halide fibers and/or if we use standard ATR accessory** (this comparison for in vitro samples, of course). Why I pay attention in my patent on IR source?-Because we have no local heating in the area of living tissue working with IR source. In the case of Raman method we will have **always** local heating (increasing of the temperature) of living tissue, at least a little bit due to laser source. That is the reason why I choose IR method which is much more difficult technically than Raman to attach the optical fibers. Why I described "intensity ratio" procedure?-Because we have different fibers, and do measurements in the different periods of times.

As for the analyzer of Krivoshlykov from CeramOptec Inc., we have to remember that any even "golden" analyzer never replace FTIR spectrometer of the entire IR spectral range. This author is not listed even the mid-IR range and have no spectra from his analyzer.

I suggested really simple way to upgrade any commercial FTIR spectrometers by special optical fibers (without any changes in the optical scheme of FTIR) for fast diagnostics of living tissue non-invasively in vivo and in a distance as I mentioned already. I did not invent any spectrometer or optical fiber. I did the unusual combination of them to get (pull out) the weak IR signals from living tissues. I checked all parameters of this new device, characteristics of spectra, and also found various and numerous applications of such optical scheme. I know that these apparatus and method are cost effective (than build any analyzers with limited characteristics). Also this method is able to save time of medical doctors specifically during surgery (I did that already) and give them fast, remote method of diagnostics at the molecular level which is very informative and more precise than we have now.

I have long-term experience (more than 35 years) in spectroscopy (many directions and methods). I know that I can help to people and medical doctors. I did that already.

My language may be is not perfect here but I am correct technically and scientifically in my patent and in this letter.

The patent can move forward my effort to apply this method. People and medical doctors need it. I checked it many times.

I hope you can understand and help me.

If you need the names and addresses of my referee I can give this information to you immediately.

I hope to hear from you soon.

Sincerely,

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